

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 04 MAY 2006

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Applicant's or agent's file reference	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2004/014755	International filing date (day/month/year) 23.12.2004	Priority date (day/month/year) 28.01.2004	
International Patent Classification (IPC) or national classification and IPC INV. C08J9/16 C08J9/28			
Applicant UNILEVER PLC et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 10 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 13.09.2005		Date of completion of this report 03.05.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Meier, S Telephone No. +49 89 2399-8312	



**INTERNATIONAL PRELIMINARY REPORT
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

2-4, 6-9, 12-14, 17

as originally filed

1, 5, 10, 11, 15, 16

received on 10.10.2005 with letter of 06.10.2005

Claims, Numbers

1-20

received on 10.10.2005 with letter of 06.10.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 18

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).
- ☒ no international search report has been established for the said claims Nos. 18
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	8-17
	No: Claims	1-9, 19, 20
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-17, 19, 20
Industrial applicability (IA)	Yes: Claims	1-17, 19, 20
	No: Claims	-

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following documents:

- D1: WO 99/00187 A (BIOPORE CORPORATION)
- D2: US-A-4 522 953 (BARBY ET AL)
- D3: US-A-4 611 014 (JOMES ET AL)
- D4: WHANG K ET AL: "A novel method to fabricate bioabsorbable scaffolds"
February 1995 (1995-02), POLYMER, ELSEVIER SCIENCE PUBLISHERS B.V,
GB, PAGE(S) 837-842 , XP004025968 ISSN: 0032-3861
- D5: US-A-5 723 508 (HEALY ET AL)
- D6: WO 2004/011537 A (UNILEVER N.V; UNILEVER PLC; HINDUSTAN LEVER
LIMITED; COOPER, ANDREW, I)
- D7: WO 2005/014704 A (THE UNIVERSITY OF LIVERPOOL; COOPER,
ANDREW; BUTLER, RACHEL)

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1.1 concerning amended dependent claim 18 of the present application: cf. reasoning on form PCT/ISA/210 of the *International Search Report* with respect to dependent claim 19 as originally filed. Amended claim 18 is based on this one.

Re Item VIII

Certain observations on the international application

2. Clarity - Art. 6 PCT

- 2.1 Expressions like "about" or similar terms like "at ambient temperature", "a period effective" or "a temperature effective" as used in claims 1 and 8 of the present application are contrary to the requirements of PCT-Guidelines 5.38.
- 2.2 It is at present not clear how a "polymeric material which is soluble in water immiscible non-aqueous media" leads to porous bodies which are dispersible in non-aqueous media. Consequently, it is reasonable to assume that the polymeric material has been crosslinked in order to make the porous bodies insoluble but dispersible in non-aqueous

media. Therefore, amended independent claim 1 of the present application is construed to include crosslinked polymer materials which are insoluble but dispersible in non-aqueous media.

- 2.3 The unit "*psia*" employed on page 8, line 23 of the description is not recognized in international practice, contrary to the requirements of R. 10.1(d) PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3. Novelty

- 3.1 The independent claim 1 of the present application claims

- a) Porous bodies which are soluble or dispersible in non-aqueous media comprising
- b) a three dimensional open-cell lattice containing 10-95 % by weight of a polymeric material which is soluble in water immiscible non-aqueous media and
- c) 5-90 % by weight of a surfactant,
- d) said porous bodies having an intrusion volume as measured by mercury porosimetry of at least $3 \text{ ml} \cdot \text{g}^{-1}$.

- 3.2 Document **D1** discloses **a)** a hydrophilic porous polymeric material comprising a **b)** a three dimensional open-cell lattice containing a water soluble polymeric material (which is certainly dispersible in organic solvents) e.g. acrylic acid, acrylamide, methylmethacrylate. Some of them have also been employed in the present application. **c)** A surfactant. The amounts are within the range of the present application. **d)** The porous polymer particles show a bulk density within the range of from $0.001\text{-}1.0 \text{ g} \cdot \text{ml}^{-1}$ and a void volume up to about 99 % as also shown in the examples of the present application. **e)** The use of polystyrene which has been crosslinked with DVB has also been disclosed. **NB** The crosslinked PS certainly fulfils the requirement that the "*polymeric material is dispersable in water immiscible non-aqueous media*" (cf. item 2.2 of this report) **f)** A process comprising a freeze drying step is not disclosed (page 9, lines 30-33; page 11, lines 30-33; page 25, lines 19-28; Examples; claims 1, 6, 18, 22, 23).

- 3.3 Therefore, claims 1-7, 20 and 21 of the present application do not fulfill the requirements

of Art. 33(1) PCT since they are not novel over the prior art document **D1** in the sense of Art. 33(2) PCT.

- 3.4** Document **D2** discloses **a)** a crosslinked homogenous porous polymeric material (cf. item **2.2** of this report) comprising **b)** polymers based on monomers like styrene and DVB **c)** a surfactant like span 80 as used in the present application. The amounts are within the range of the present application. **d)** The porous material shows a pore volume of more than $9 \text{ ml} \cdot \text{g}^{-1}$. **e)** The material is suited to incorporate liquids like bleaches, etc. **f)** A process comprising a freeze drying step is not disclosed (abstract; column 2, lines 31-59; column 3, line 16-column 6, line 60; claims 1, 3, 6, 8; Examples).
- 3.5** Therefore, claims 1-7, 20 and 21 of the present application do not fulfill the requirements of Art. 33(1) PCT since they are not novel over the prior art document **D2** in the sense of Art. 33(2) PCT.
- 3.6** Document **D3** discloses **a)** highly porous crosslinked functionalised polymers (cf. item **2.2** of this report) comprising **b)** polymers based on monomers like styrene and/or methacrylate containing various ionic or polar functional groups **c)** a surfactant like span 80 as used in the present application. The amounts are within the range of the present application. **d)** The porous material shows a pore volume of greater than $5.6 \text{ ml} \cdot \text{g}^{-1}$. **e)** The material is suited to incorporate liquids. **f)** A process comprising a freeze drying step is not disclosed (abstract; column 1, lines 25-33; column 2, lines 67 and 68; column 3, line 40-column 4, line 35; claims 1, 6).
- 3.7** Therefore, claims 1-7, 20 and 21 of the present application do not fulfill the requirements of Art. 33(1) PCT since they are not novel over the prior art document **D3** in the sense of Art. 33(2) PCT.
- 3.8** It is pointed out that documents **D6** and **D7** which have been cited in the ISR as a "*P*" and "*E*" document, respectively, might be relevant to the question of novelty in case that the application enters a regional and/or national phase.

4. Inventive Step

- 4.1** The working-up of HIPE by freeze drying to porous polymer materials is generally known in the art and can be found in documents **D4** and **D5** for example. The documents are concerned with the production of highly porous bioabsorbable scaffolds and explicitly describe the same process for producing the same by freeze drying and also teach the use of surfactants like polyethylene glycol (e.g. **D5**, column 3, lines 45-50).

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- 4.2 Therefore, amended claims 8-17 do not fulfill the requirements of Art. 33(1) PCT since they do not involve an inventive step in the sense of Art. 33(3) PCT.
- 4.3 Since amended claims 1-7, 19 and 21 of the present application do not fulfil the requirements of Art. 33(2) PCT as to novelty, they cannot involve an inventive step in the sense of Art. 33(3) PCT.

5. Industrial Applicability

- 5.1 The subject matter of amended claims 1-17, 19 and 20 is industrial applicable.